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Shared decision-making for prostate cancer screening and treatment: a systematic review of randomised controlled trials

Martínez-González, Nahara Anani ; Plate, Andreas ; Senn, Oliver ; Markun, Stefan ; Rosemann, Thomas ;
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Abstract: **INTRODUCTION:** Men facing prostate cancer screening and treatment need to make critical and highly preference-sensitive decisions that involve a variety of potential benefits and risks. Shared decision-making (SDM) is considered fundamental for "preference-sensitive" medical decisions and it is guideline-recommended. There is no single definition of SDM however. We systematically reviewed the extent of SDM implementation in interventions to facilitate SDM for prostate cancer screening and treatment. **METHODS:** We searched Medline Ovid, Embase (Elsevier), CINHAL (EBSCOHost), The Cochrane Library (Wiley), PsychINFO (EBSCOHost), Scopus, clinicaltrials.gov, ISRCTN registry, the WHO search portal, ohri.ca,.opengrey.eu, Google Scholar, and the reference lists of included studies, clinical guidelines and relevant reviews. We also contacted the authors of relevant abstracts without available full text. We included primary peer-reviewed and grey literature of randomised controlled trials (RCTs) reported in English, conducted in primary and specialised care, addressing interventions aiming to facilitate SDM for prostate cancer screening and treatment. Two reviewers independently selected studies, appraised interventions and assessed the extent of SDM implementation based on the key features of SDM, namely information exchange, deliberation and implementation. We considered bi-directional deliberation as a central and mandatory component of SDM. We performed a narrative synthesis. **RESULTS:** Thirty-six RCTs including 19 196 randomised patients met the eligibility criteria; they were mainly conducted in North America (n = 28). The median year of publication was 2008 (1997-2015). Twenty-three RCTs addressed decision-making for screening, twelve for treatment and one for both screening and treatment for prostate cancer. Bi-directional interactions between healthcare providers and patients were verified in 31 RCTs, but only 14 fulfilled the three key SDM features, 14 had at least "deliberation", one had "unclear deliberation" and two had no signs of deliberation. **CONCLUSIONS:** There is significant variation in the extent of SDM implementation among studies addressing SDM for prostate cancer screening and treatment. Further evaluation of these results on patient outcomes, a standardised SDM definition and guidance for an effective implementation in several clinical settings are needed.

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Shared decision-making for prostate cancer screening and treatment: a systematic review of randomised controlled trials

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Summary

INTRODUCTION: Men facing prostate cancer screening and treatment need to make critical and highly preference-sensitive decisions that involve a variety of potential benefits and risks. Shared decision-making (SDM) is considered fundamental for “preference-sensitive” medical decisions and it is guideline-recommended. There is no single definition of SDM however. We systematically reviewed the extent of SDM implementation in interventions to facilitate SDM for prostate cancer screening and treatment.

METHODS: We searched Medline Ovid, Embase (Elsevier), CINHAL (EBSCOHost), The Cochrane Library (Wiley), PsychINFO (EBSCOHost), Scopus, clinicaltrials.gov, ISRCTN registry, the WHO search portal, ohri.ca, open-gre.eu, Google Scholar, and the reference lists of included studies, clinical guidelines and relevant reviews. We also contacted the authors of relevant abstracts without available full text. We included primary peer-reviewed and grey literature of randomised controlled trials (RCTs) reported in English, conducted in primary and specialised care, addressing interventions aiming to facilitate SDM for prostate cancer screening and treatment. Two reviewers independently selected studies, appraised interventions and assessed the extent of SDM implementation based on the key features of SDM, namely information exchange, deliberation and implementation. We considered bi-directional deliberation as a central and mandatory component of SDM. We performed a narrative synthesis.

RESULTS: Thirty-six RCTs including 19 196 randomised patients met the eligibility criteria; they were mainly conducted in North America ($n = 28$). The median year of publication was 2008 (1997–2015). Twenty-three RCTs addressed decision-making for screening, twelve for treatment and one for both screening and treatment for prostate cancer. Bi-directional interactions between healthcare providers and patients were verified in 31 RCTs, but only 14 fulfilled the three key SDM features, 14 had at least “deliberation”, one had “unclear deliberation” and two had no signs of deliberation.

CONCLUSIONS: There is significant variation in the extent of SDM implementation among studies addressing SDM for prostate cancer screening and treatment. Further evaluation of these results on patient outcomes, a standardised SDM definition and guidance for an effective implementation in several clinical settings are needed.

Key words: systematic review, shared decision-making, prostate cancer, screening, treatment, randomised controlled trials

Introduction

Prostate cancer is one of the most serious public health concerns relating to men’s health worldwide. The World Health Organization (WHO) has declared prostate cancer to be the second most commonly diagnosed type of cancer in men, and the fifth leading cause of death due to cancer in men worldwide [1]. It accounts for 6.6% of the total deaths of men, and the burden is expected to increase to 1.7 million cases and 499 000 new deaths by 2030 globally [2]. Prostate cancer incidence varies widely in the world with higher rates (mostly) in high-income countries [1], mainly due to the widespread use of screening tests, which have improved early detection, but whose benefits and harms are controversial [3, 4]. There is no consensus on the general screening routine, including the age at which screening should be performed [5–9], and testing has led to false-positive results and over diagnosis [10]. Furthermore, patients often face more than one alternative treatment, which represent a variety of benefits and risks without convincing evidence indicating a best choice [11]. The survival benefit comes at the price of considerable morbidity, highly impaired quality of life, psychological distress and increased healthcare costs due to treatment [10, 12]. With these precedents, the individual patient’s situation becomes preference sensitive, requiring careful consideration and deliberation of many factors (e.g., diagnosis, prognosis, fears, values, beliefs, ethics, hopes and previous experience) that make decisions complex and highly preference sensitive. Shared decision-making (SDM) is frequently advocated in clinical practice as the fundamental component of all patient-provider interactions in regards to medical decisions [13, 14] since it is based on the principles of patient-cen-

Author contributions
NAMG wrote the manuscript. NAMG, OS and SNJ conceived and designed the review. NAMG designed the data extraction forms. NAMG, AP, SM, OS and SNJ tested the data extraction forms, screened and selected studies. NAMG and AP extracted and verified the data. NAMG, AP, SM, SNJ performed the studies assessment. NAMG performed the analyses. TR revised the manuscript and contributed to its improvement. All authors revised and contributed to improving the manuscript, and read and approved the final manuscript.

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tred care [15, 16]. It is particularly recommended for “preference-sensitive medical decisions” [17] and considered essential for screening and treatment of prostate cancer [18, 19]. With this approach, the decision depends to a great extent on the patients’ informed preferences and on their value of risks, benefits and harms of options [17]. These attributes are often integrated and tailored to the patient’s circumstance by means of decision aids or other methods [20–23] that facilitate SDM [16]. However, there is no single definition of SDM and no clear consensus about how to conduct SDM in routine medical practice. Ongoing debate also indicates that the goal of SDM is not yet clarified. Some view SDM as a partnership between patient and/or patient care-related parties (e.g., legal guardian, relatives) and healthcare providers to equally share decisions about healthcare choices [24–27]. For others, SDM is a process to engage in decision-making [14, 28], or an approach to incorporate preference-sensitive elements that facilitate decision-making [17].

SDM appeals greatly to policy makers and healthcare providers because of its potential to reduce the overuse of options with unclear benefits [29] while enhancing the use of beneficial options [30] and reducing variations in practice [31]. We performed a systematic review to assess the extent of SDM implementation in studies of interventions aiming to facilitate SDM for men facing prostate cancer screening and/or treatment decisions.

Methods

We developed a protocol before starting the review following the principles for systematic reviews [32, 33], and we report the methods in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines (see [table S1](#) in appendix 1 for the PRISMA checklist) [34].

Inclusion and exclusion criteria

We focused on the extent to which the concept of SDM is implemented in clinical practice. We assessed the reported SDM interventions based on the SDM model (see section “Assessment of SDM implementation”). We broadly defined SDM interventions as the approaches, methods or tools designed to facilitate, foster, or improve patient-healthcare provider involvement in medical decision-making, based on Charles et al. [35]. We included peer-reviewed and grey literature of studies reported in English addressing (the effectiveness of) SDM interventions for men facing decisions about prostate cancer screening and/or treatment. Eligible studies were randomised controlled trials (RCTs), quasi-RCTs (method of allocation not strictly random), and cluster RCTs (1) comparing SDM interventions to one or more alternative interventions, and/or usual care, (2) directed at patients and/or their care-related parties and/or healthcare providers, and (3) conducted in primary or specialised healthcare including general practices, community clinics, ambulatory care, hospitals and private care services. Studies were included regardless of the length of follow-up, publication year and country of origin. We excluded studies conducted in non-clinical settings and community studies in which discussions were not intended or could not occur.

Search strategy and data sources

We designed and conducted a comprehensive search strategy in Medline Ovid, Embase (Elsevier), CINHAL (EBSCOHost), The Cochrane Library (Wiley), PsychINFO (EBSCOHost) and Scopus from their inception to March 2015. The search strategy was revised by an information specialist and, included terminology compatible with SDM (e.g., “patient participation” and “patient involvement”), “shared decision making” and “prostate cancer” (see [table S2](#) in appendix 1). It was not restricted by publication date, language, country or outcomes, and included a study design filter for the identification of RCTs in humans [36]. We also searched for grey literature using individual clinical trial registers (clinicaltrials.gov and [ISRCTN](http://isrctn.com)), the WHO search portal (<http://apps.who.int/trialsearch>), and the Ottawa Hospital Research Institute website (<http://www.ohri.ca>). The records were accessed between February and August 2016, and the trials registration number was additionally searched for by use of Medline and PubMed. We also used Google Scholar and the system for Information on Grey Literature in Europe (<http://open-grey.eu/>). We identified additional studies by screening the reference lists of included studies, relevant systematic reviews and clinical guidelines, and by contacting (June 2015 to January 2017) the authors of potentially eligible abstracts for which the full text could not be located.

Selection of studies

Two reviewers independently screened the titles and abstracts of all citations, and examined the full text of potentially eligible publications meeting the eligibility criteria. Studies reported in more than one publication were identified and treated as one unit. We resolved differences through consensus or by involving an arbitrator.

Data collection and synthesis

One reviewer extracted data using standardised data collection forms designed and developed *a priori*. A second reviewer independently verified data extractions, resolving differences by consensus or by involving an arbitrator. For each study, we extracted information on the bibliographic details of studies (design, country, time of study conduct, funding sources), characteristics of study populations and interventions, including the interventions’ attributes, and the elements and key features of SDM implementation. Data from a single study reported across various publications were extracted as one unit. We obtained full-text data from the authors of potentially eligible abstracts without available full text. In this review, we performed a narrative synthesis of the results, including a description of the reported SDM interventions and their implementation based on the SDM model. In a future report, we will include an analysis of the effectiveness of SDM interventions.

Assessment of the extent of SDM implementation

We evaluated the extent of SDM implementation in accordance with the essential characteristics of SDM proposed by Charles et al. [35] (see [table S3](#) in appendix 1). Of the analytic stages of SDM, we considered deliberation to be central and mandatory, and that it must be bi-directional (i.e., active participation of both patient and healthcare provider) for SDM to occur. Provision of information only,

such as use of decision aids, cannot replace this active and bi-directional participation, but such strategies in a “stand-alone” format can facilitate SDM or become a component of a multi-faceted intervention. To differentiate the variants (e.g., two-way from one-way) in decision-making, we assessed the intervention’s description and content, its delivery procedure and the mode of decisions to identify the elements aiming to facilitate decision-making. We evaluated whether:

1. The intervention aimed to facilitate or foster shared decisions, for example by including elements of patient activation, encouragement to talk or discuss, etc.
2. There was evidence of bi-directional interaction between patients and healthcare providers, such as planned (telephone or face-to-face) consultations.
3. Implementation of decision-making was based on three key features of SDM [35], i.e., patient and healthcare provider:
 - a. share/exchange information,
 - b. deliberate, and
 - c. make/implement a decision in consensus.

Ideally, this collection of behaviours occurs altogether within a clinical encounter [35]. We anticipated, however, that SDM definitions and goals would differ among studies resulting in heterogeneous decision-making behaviours in which SDM might not be achieved. We classified the interventions as SDM (all criteria met), partial SDM (at least deliberation met), unclear (unclear deliberation), and no SDM (unidirectional interaction) by coding 3a, 3b and 3c as one if the criteria was met, zero if the criteria was not met, or unclear (?) if criteria details were not reported or could not be verified. Table S4 (appendix 1) illustrates this system.

We considered the following criteria as components of SDM, since these were intended to encourage discussions between patient and healthcare provider or implied a bi-directional interaction between them: patient activation strategies such as provision of information, patient prompts, clinical encounters that occurred at or shortly before a healthcare appointment, coaching, interviews, or before filling out questionnaires.

Results

Identification of eligible studies

Our searches identified 15 398 records. After perusal of all titles and abstracts, we excluded 15 128 records. We examined in detail the full text of 270 potentially relevant articles. After excluding 220 articles, 36 RCTs reported in 50 publications met the inclusion criteria [37–86]. Figure 1 shows the flow of study identification and selection. Characteristics of study, population and interventions of the 36 RCTs are summarised in supplementary table S5 (appendix 1).

Study and population characteristics

The 36 RCTs were published from 1997 to 2015, and 44.4% (n = 16) were published between 2010 and 2015; the median year of publication was 2008 (table 1). The vast majority (77.8%) of RCTs were conducted in North America (n = 28), and the remaining (22.2%) in Europe (n

= 7) and Australia (n = 1). Thirty-five parallel RCTs included 18 484 randomised patients, and the cluster RCT randomised 712 patients with 120 physicians and 55 waiting areas. Twenty-three (63.9%) RCTs addressed decision-making for prostate cancer screening. Of those, only five (21.7%) defined screening as both testing for prostate-specific antigen (PSA) and a digital rectal examination (DRE); the other eighteen (78.3%) defined prostate cancer screening as testing for PSA only. Twelve (33.4%) RCTs addressed decision-making for prostate cancer treatment. Nine (75%) of those provided a range of treatment options of which surgery (n = 9) was the most commonly offered choice, followed by radiotherapy (external beam radiation; n = 7), watchful waiting (n = 6), brachytherapy (n = 6) and hormone therapy (n = 4). One RCT addressed decision-making for both screening and treatment of prostate cancer [86]. Thirty-two (88.9%) RCTs included patient-directed interventions, but four RCTs targeted both patients and their significant other (e.g., relatives, spouses) [83, 84], or patients and physicians [42, 45].

Patients were mainly recruited from primary care clinics in 20 (55.6%) RCTs (table 2). In the other 16 (44.4%) RCTs, patients were recruited from hospital-based (n = 5) or cancer (n = 3) clinics, a specific population (n = 1), or from multidisciplinary (combining at least two; n = 7) settings. Thirty (83.4%) RCTs reported the targeted age of participants. In 27 RCTs (75%), the minimum and maximum targeted age of men was 40 and 86 years, respectively; one RCT (3%) targeted relatively young (younger than typically recommended) men who were at least 18 years old [82]; and two RCTs (5.6%) did not use age as an eligibility criterion for participants [68, 74]. Three RCTs were not tied to a consultation [38, 48, 57], but the type of participating healthcare providers was reported in 24 (66.7%) RCTs: 14 RCTs (38.8%) employed faculty, general or internal medicine physicians, and nurse practitioners; and 10 RCTs (27.8%) employed physician specialists (urology, oncology, and/or radiation oncology). Eleven (30.6%) RCTs reported the number of participating healthcare providers, which ranged from 2 [85] to 127 [54]. Seven RCTs (21.2%) reported the level of healthcare providers’ training or experience, which ranged from post-graduate practice to 40 years of experience, or board-certified physicians. Thirty-four RCTs reported the funding sources; these were non-profit governmental and private institutions.

Attributes of decision-making interventions

The interventions varied widely in their delivery mode, form, and content (table 3). SDM was considered within the context of primary care in 55.5% (n = 20) of the RCTs, multidisciplinary healthcare in 19.4% (n = 7), hospital care in 14.0% (n = 5), specialised care in 8.3% (n = 3), and from a population perspective in 2.8% (n = 1). The interventions were delivered on-site (n = 14), home (n = 9), on-site or home (n = 9), home or on-site combined with other settings (n = 3), and face-to-face or by telephone (n = 1). Most interventions (n = 28) were delivered before consultations, interviews or questionnaires, and a few were delivered during (n = 6) or after (n = 2) consultations or questionnaires. The interventions were self-administered in 20 (55.6%) RCTs, exclusively delivered by clinicians or re-

search staff in 10 (27.8%) RCTs, and either delivered by research staff or clinicians guided patients in 6 (16.7%) RCTs.

A multifaceted strategy was used in nearly half (47.2%) of the studies. Most interventions included material in paper-based ($n = 25$) format although some included web-based ($n = 4$), paper- and web-based ($n = 2$), or other format (e.g., interview, audiotape recording; $n = 5$). Healthcare literacy levels were considered in the development or pilot testing of the interventions in 19 RCTs (52.8%). Of these, one RCT exclusively developed separate interventions for low and high health literacy [51]; in two RCTs interventions were designed for low health-literacy populations [46, 54]; one RCT considered the target population with a literacy expert [58]; and one RCT used tailored literacy with a decision navigator [72].

Elements and key features of SDM interventions

Twenty-five RCTs (70%) intended to assess SDM to some degree (table 4). This intention was not clearly stated in the other 11 RCTs (30%), although the interventions included elements to facilitate or foster SDM in all but one study. “Informed decision-making” was the most frequently ($n = 21$) used term, whereas only 9 (25%) RCTs used

the term SDM. The studies also referred to other terms and measurements relevant to SDM including “weighing up benefits and harms”, “risks”, “pros and cons of options”, “patients’ values”, “preferences”, “promotion of engagement”, “discussions of choices”, “activation” or “participation in decision-making appointments”, “decision role” (e.g., active, passive), “patient autonomy”, “patient centredness”, “knowledge and beliefs”, and “decisional conflict”. The interventions varied widely in the operational framework underlying their development, with the Ottawa Decision Support Framework ($n = 5$) being the most common among the 23 RCTs that reported using a framework. Other frameworks included the health belief model theory ($n = 2$), the US Preventive Services Task Force ($n = 2$), the Patient Centred ($n = 2$), and another twelve ($n = 12$) approaches.

The extent of SDM implementation varied widely among studies (tables 2 and 4). Overall, 31 (86.1%) RCTs were verified as showing bi-directional interactions between patient and healthcare provider. Of these, 28 (77.8%) RCTs showed bi-directional interactions for information exchange and deliberation, but only 14 (50%) were verified as having built consensus for decisions about screening or treatment options. Of the 31 (86.1%) RCTs in which deci-

Figure 1: Identification and selection of studies.

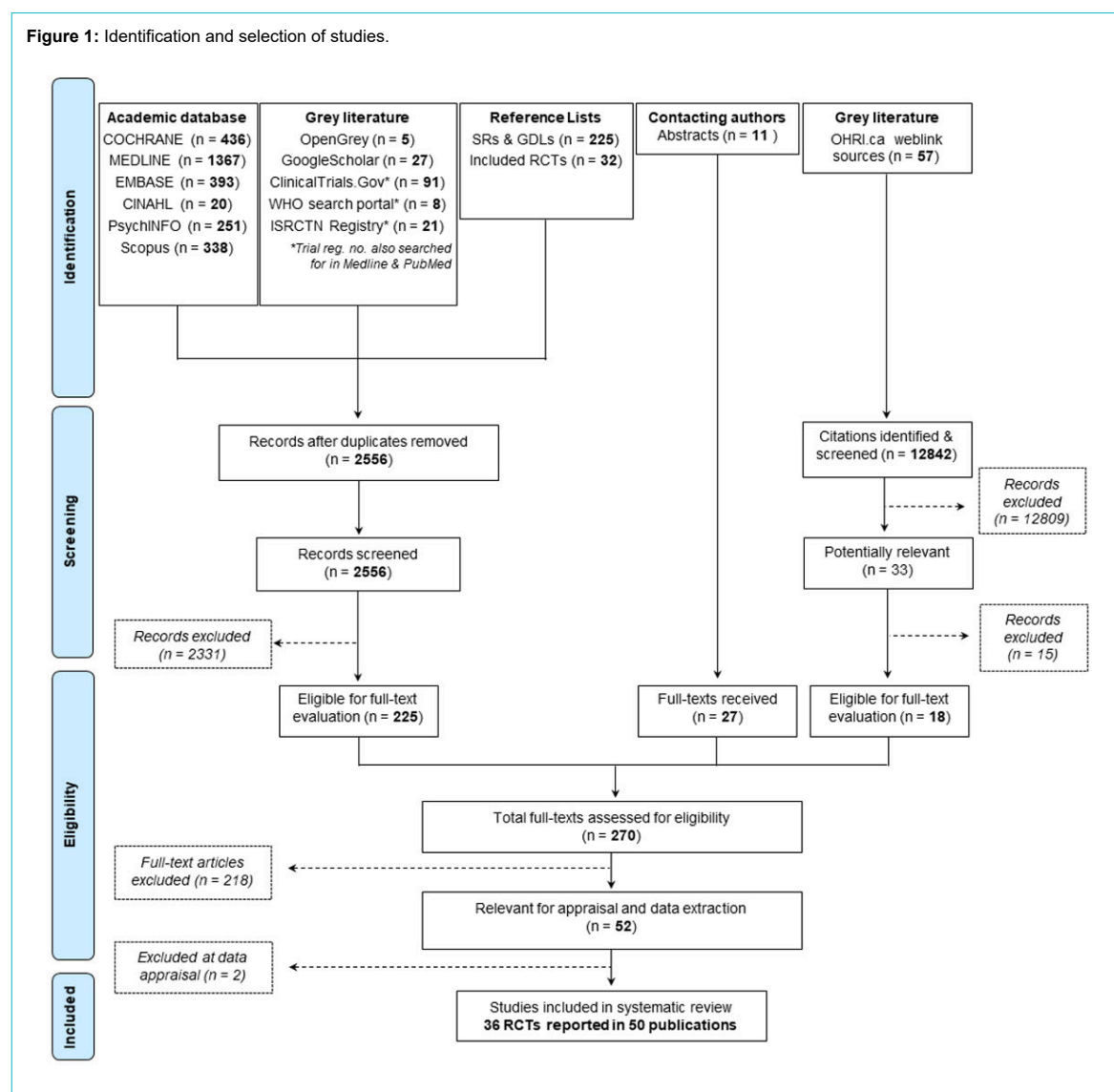


Table 1: Summary of the characteristics of 36 randomised controlled trials of decision-making interventions for prostate cancer.

Year of publication, mean (range)			2008 (1997–2015)
Studies included			
35 parallel RCTs, randomised participants, n (range)			18 484 (60–3327)
1 cluster RCT, randomised participants, n (55 waiting areas)			712 patients; 120 physicians
Country of studies			
North America			
USA			22 (61%)
Canada			6 (17%)
Europe			
United Kingdom			3 (8%)
The Netherlands, Finland, Spain, Greece			4 (12%)
Australia			1 (3%)
Decision context			
Screening			23 (64%)
PSA only			18 (50%)
PSA and DRE			5 (14%)
Treatment*			12 (33%)
Radical surgery			9 (100%)
Radiotherapy			7 (78%)
Brachytherapy			6 (67%)
Watchful waiting			6 (67%)
Hormone therapy			4 (44%)
No treatment			2 (22%)
Other†			7 (78%)
Screening and treatment: PSA only; surgery, radiotherapy, watchful waiting			1 (3%)
Age of study participants, range (years)			18–86
Number and specialty of participating healthcare providers‡, n (range)			2–127
Primary care providers: GPs or NPs			14 (58%)
Urology or oncology physicians			10 (42%)
Intervention			
Target population			
Patients			32 (89%)
Patients and partners or family members			2 (6%)
Patients and physicians			2 (6%)
Fostering of SDM			
Intervention elements for fostering SDM			35 (97%)
Bi-directional interaction (physician ↔ patients) e.g., tied to consultations			31 (86%)
Key features of SDM			
a) Information exchange (physician ↔ patients)			28 (78%)
b) Deliberation (physician ↔ patients)			28 (78%)
c) Implementation (physician ↔ patients)			14 (39%)
Intervention class¶	Screening	Treatment	Screening and treatment
1. SDM	8 (35%)	6 (50%)	
2. Partial SDM	10 (43%)	3 (25%)	1 (100%)
3. Unclear	2 (9%)	1 (8%)	
4. No SDM	3 (13%)	2 (17%)	

DRE = digital rectal examination; GPs = general practitioners (faculty, general or internal medicine physicians); NPs = nurse practitioners; PSA = prostate-specific antigen; RCT = randomised controlled trial; SDM = shared decision-making. Data are presented as n (%) unless otherwise stated. * Treatment options reported in nine of the twelve RCTs on treatment. † Cryotherapy, pelvic lymph node dissection, transurethral resection, complementary, no preference, undecided, missing, "other". ‡ Number of healthcare providers reported in eleven RCTs, and the specialty of healthcare providers was reported in 24 RCTs. ¶ SDM key features [a-b-c] coded as: 1 = criteria met, 0 = criteria not met, or ? = unclear (see [table S4](#) in appendix 1).

sion-making involved at least two parties, 45.2% (screening, n = 8; treatment, n = 6) fulfilled the three key SDM features: nine considered SDM within the context of primary care and five within the context of hospital and/or specialised care. Another 45.2% (screening, n = 10; treatment, n = 3; screening and treatment, n = 1) met the criteria for partial SDM (verified deliberation); 3.2% (treatment, n = 1) had all key SDM features difficult to verify (unclear deliberation), and 6.4% (screening, n = 1; treatment, n = 1) had the characteristics of no SDM. The other five (13.9%) of the 36 included RCTs, showed unclear de-

liberation (screening, n = 1; treatment, n = 1) or no SDM (screening, n = 2; treatment, n = 1).

Discussion

In this systematic review, we identified 36 RCTs of interventions aiming to facilitate SDM for screening and treatment of prostate cancer in a variety of settings and populations. The majority of RCTs were from North America, mainly the USA (n = 22). Most of the participating men were 40 to 86 years old and more than half (55.6%) were recruited from primary care. There was a wide variation in

Table 2: Characteristics of 36 randomised controlled trials of decision-making interventions for prostate cancer.

First author, publication year [reference]	Country	Decision context	Setting and facilities, n	Target population and patients' target age (range), years	Intervention group, randomised (n)	Control group(s), randomised (n)	Participating HCP and specialty, n
Screening							
Lewis, 2015 [37]	USA	PSA	PCs, 7 PC AGIMP, 1	Patients 50–75	n = 831	1) n = 840 2) n = 828 3) n = 828	Mid-level healthcare provider, n = n.r.
Tomko, 2015 [38–41] (Starosta, 2015; Tomko, 2015; Taylor, 2013)	USA	DRE and PSA	UH, 1 Hospital centre, 1 Medstar PP, 1	Patients 45–70	n = 631	1) n = 630 2) n = 632	Not tied to a consultation - interviewers, n = n.r.
Wilkes, 2013 [42]	USA	PSA	AMC PC Net, 2 Staff model HMO, 2 MGPNET, 1	Patients and physicians 55–65	n = 19 waiting areas, 113 patients, 36 physicians	1) n = 19 waiting areas, 246 patients, 41 physicians 2) n = 17 waiting areas, 353 patients, 43 physicians	Physicians in internal and family medicine (4–40 years' experience since clinical training completed), n = 120
Williams, 2013 [43]	USA	PSA	UMC, 1 UCaC, 1	Participants 40–70	n = 138	1) n = 134 2) n = 137 3) n = 134	Urology physicians or oncologists, n = n.r.
Landrey, 2013 [44]	USA	PSA	UH GIMPs, 2	Patients 50–74	n = 145	1) n = 158	Internal medicine physicians, 44
Sheridan, 2012 [45]	USA	PSA	AGP, 2 Community practice, 2	Patients (and physicians) 40–80	n = 60	1) n = 70	Family physicians, 28
Lepore, 2012 [46]	USA	PSA	IC beneficiaries healthcare workers' union, 1	Patients 45–70	n = 244	1) n = 246	Primary care physician
Myers, 2011 [47]	USA	PSA	PCs, 2	Patients 50–69	n = 156	1) n = 157	Family physicians (board-certified practitioners), 22
Evans, 2010 [48]	UK (South Wales)	PSA	GPs (from 9 local health board areas), 25	Patients 50–75	n = 129	1) n = 126 2) n = 127 3) n = 132	Not tied to a consultation
Stamatiou, 2008 [49]	GRC	PSA	PC institutions	Patients 50–86	n = 548	1) n = 587	Physicians, n = n.r.
Frosch, 2008 [50]	USA	PSA	Prev medicine clinic (KP), 1	Patients >50	n = 155	1) n = 153 2) n = 152 3) n = 151	Physicians, n = n.r.
Volk, 2008 [51]	USA	PSA	HGP (low HL site), 1 UGP (high HL site), 1	Patients 40–70 if AA or 50–70 if not AA	n = 224	1) n = 226	Physicians, n = n.r.
Krist, 2007 [52, 53] (Woelf, 2005)	USA	PSA	Suburban GP, 1	Patients 50–70	n = 226	1) n = 196 2) n = 75	Family physicians, 29 (13 faculty, 8 second-year residents, and 8 third-year residents)
Kripalani, 2007 [54]	USA	DRE and PSA	Teaching hospital, 1	Patients 45–70	n = 101	1) n = 101 2) n = 101	Nurse practitioners, 5; internal medicine physicians, 109 (post-graduate year 1, 2, or 3 under the supervision of board-certified internal medicine faculty); faculty physicians, 13 (fully trained)
Partin, 2006 [55, 56] (Partin, 2004)	USA	PSA	VA GIMP, 4	Patients ≥50	n = 384	1) n = 384 2) n = 384	General internal medicine physicians, n = n.r.
Watson, 2006 [57]	UK (England and Wales)	PSA	GPs, 11	Patients 40–75	n = 980	1) n = 980	Not tied to a consultation
Myers, 2005 [58]	USA	DRE and PSA	Community-based PC, 3	Patients >40	n = 121	1) n = 121	Family physicians, 4; internal medicine physicians, 2; oncologist, 1
Gatellari, 2003 [59]	AUS	PSA	Urban GPs, 13	Patients 40–70	n = 126	1) n = 122	Family physicians, 13
Frosch, 2003 [60, 61] (Frosch, 2001)	USA	PSA	Prev medicine clinic, 1	Patients >50	n = 114	1) n = 112	Physicians, n = n.r.
Volk, 2003 [62, 63] (Volk, 1999)	USA	PSA	UGP, 1	Patients 45–70	n = 80	1) n = 80	Primary care provider, n = n.r.
Schapiro, 2000 [64]	USA	DRE and PSA	VA outpatient clinic, 1	Patients 50–80	n = 122	1) n = 135	Physician or research physicians (investigators), n = n.r.
Davison, 1999 [65]	CAN	DRE and PSA	FM teaching centre, 1	Patients 50–79	n = 50	1) n = 50	Family physicians (first and second year residents and academic staff), n = n.r.
Wolf, 1998 [66, 67] (Wolf, 1996)	USA	PSA	UGPs, 4	Patients ≥50	n = 103	1) n = 102	Primary care physicians, n = n.r.

First author, publication year [reference]	Country	Decision context	Setting and facilities, n	Target population and patients' target age (range), years	Intervention group, randomised (n)	Control group(s), randomised (n)	Participating HCP and specialty, n
Treatment							
Chabrera, 2015 [68]	SPN	n.r.	UH, 1 Oncology institutes, 2	Patients >45	n = 73	1) n = 74	Urology physicians, radiation oncology physicians, medical oncology physicians, n = n.r.
Berry, 2013 [69–71] (Berry, 2012; Bosco, 2012)	USA	1, 5, 6, 8, 13, 14	VA hospital, 3 UCaC, 1 Ca institute, 2	Patients >40	n = 266	1) n = 228	Physician consultants (urology or oncology physician or other), n = n.r.
Hacking, 2013 [72]	UK (Scotland)	1, 5, 6, 7, 8	GH, 1	Patients Age, n.r.†	n = 63	1) n = 60	Urology physicians or oncologists, n = n.r.
van Tol-Geerdink, 2013 [73]	NLD	1, 5, 6, 11	UMC, 1 GHs, 2	Patients Age, n.r.†	n = 163	1) n = 77	Urology physicians, n = n.r.
Huang, 2014 [74–76] (Auvinen, 2004; Auvinen, 2001)	FIN	1, 5, 7, 8	UHs, 2 GHs, 2	Patients All‡	n = 104	1) n = 106	Urology physicians (board-certified), 4
Feldman-Stewart, 2012 [77–79] (Feldman-Stewart, 2004; Feldman-Stewart, 2001)	CAN	1, 2, 5, 6, 10, 12, 14	Ca clinic centres, 4	Patients >40	n = 81	1) n = 75	Physicians, n = n.r.
Taylor, 2010 [80]	USA	1, 5, 6, 7, 8, 11	UH, 1 Hospital centre, 1 Local PC support groups and newsletters	Patients All‡	n = 66 (95 CD users)	1) n = 66 (25 non-CD users)	Urology physicians, radiation oncology physicians, medical oncology physicians, n = n.r.
Mishel, 2009 [81]	USA	n.r.	Ca centre, 2 Community hospital, 3 VA medical centre, 1	Patients Age, n.r.†	n = 89	1) n = 93 2) n = 74	Physicians, n = n.r.
Hack, 2007 [82]	CAN	1, 4, 7, 8, 10	Tertiary oncology clinic treatment facilities, 4	Patients >18	n = 214	1) n = 211	Fully trained radiation oncologists, n = 15
Davison, 2007 [83]	CAN	1, 2, 5, 6, 8, 9	GH-based prostate education and research centre, 1	Patients and partners Age, n.r.†	n = 162	1) n = 162	Urology physicians, n = n.r.
Feldman-Stewart, 2006 [84]	CAN	n.r.	Ambulatory Ca centres, 3	Patients and family members Age, n.r.†	n = 152	1) n = 156	Physicians, n = n.r.
Davison, 1997 [85]	CAN	1, 3, 12	Community clinic with practicing urologists, 1	Patients Age, n.r.†	n = 30	1) n = 30	Urology physicians, 2
Screening and treatment							
Wilt, 2001 [86]	USA	1, 5, 8	PCs at VA centre, 1	Patients ≥50	n = 275	1) n = 275	Physicians, n = n.r.

CAN = Canada; NLD = The Netherlands; SPN = Spain; FIN = Finland; GRC = Greece. LPC = localised prostate cancer; DRE = digital rectal examination; PSA = prostate-specific antigen; AA = African American; n.r. = not reported; CD = CD-ROM-based decision aid. Settings: VA = Veterans' affair; PC = primary care clinics/practices; GIMP = general internal medicine practice; AGIMP = academic general internal medicine practice; UH = university hospital; MGP = medical group practice; PP = physician partners; HMO = health maintenance organisations; AMC = academic medical centre; Net = networks; UMC = university medical centre; UCaC = university cancer centre; AGP = academic general practice; GH = general hospital; FMC = family medicine centre/clinic; IC = insurance company; GPs = general/family medicine practices/clinics; Prev = preventive; KP = Kaiser Permanente; UGP = university-affiliated general practice; HGP = hospital-based general practice; HL = health literacy. Treatment options: 1 = radical surgery (prostatectomy or "surgery"), 2 = cryotherapy (cryosurgery or cryoablation), 3 = lymphadenectomy (lymph node dissection), 4 = transurethral resection of the prostate, 5 = radiotherapy, 6 = brachytherapy (combination of radiotherapy and surgery), 7 = hormone therapy (e.g., orchiectomy, LHRH agonist treatment, antiandrogen or oestrogen), 8 = watchful waiting or active monitoring, 9 = complementary, 10 = no treatment, 11 = no treatment, preference, 12 = other (type not stated), 13 = undecided, 14 = missing. * Cluster RCT. † RCTs for which no specific target age was used as eligibility criterion. ‡ RCTs for which age was not used as eligibility criterion.

the minimum age (range: 40–55) at which men were targeted to be screened for prostate cancer with starting cut-off ages at 40, 45, 50, 55 years, and 18 years in one study. Primary care physicians or nurse practitioners participated in at least a third of the studies, whereas specialised physicians participated in less than a third of the studies. Most studies addressed decision-making for prostate cancer screening, with PSA being the most (78.3%) frequently used method of diagnosis. The interventions differed widely in delivery mode, format and content. Our approach for assessing the implementation of SDM interventions was based on the criteria defined by Charles et al. [24, 35]. The model distinguishes the roles and responsibilities of the relationship between patient and health-

care provider for SDM compared with other models of decision-making. The essential characteristic of SDM is the bi-directional interaction between patient and healthcare provider which places SDM in the middle between a paternalistic and an informed-decision approach. Patients (and/or related parties) and healthcare providers need to actively adopt a set of behaviours in each of the analytic stages, namely information exchange, deliberation and decision implementation [35]. Our approach also supports deliberation as the key feature to accomplish SDM in routine practice, in keeping with Elwyn et al. [87]. We found that different strategies are used to encourage participation in decision-making, and interventions might be considered to facilitate SDM, although they might not

Table 3: Characteristics of decision-making interventions for prostate cancer screening and treatment.

First author, publication year [reference]	Healthcare context	Strategy	Format and delivery mode	Delivery time and location	Health literacy or numeracy	Intervention and randomised patients, n	Comparator(s) and randomised patients, n
Screening							
Lewis, 2015 [37]	General medicine	Single vs multifaceted	<ul style="list-style-type: none"> DVD and/or letter in paper format Self-administered 	<ul style="list-style-type: none"> Before consultation On-site clinic or home 	Unclear/n.r.	DVD DESI; n = 831	1) Invitation to participate in SMA appointment with provider and other patients; n = 840 2) PSA DVD DESI + SMA; n = 828 3) No additional intervention material; n = 828
Tomko, 2015 [38–41] (Starosta, 2015; Tomko, 2015; Taylor, 2013)	Multidisciplinary (hospital and specialised)	Single	<ul style="list-style-type: none"> Web-based and print-based Self-administered 	<ul style="list-style-type: none"> Before telephone interview (1 mo) (not tied to consultation) Home 	Yes	Web-based DA; n = 631	1) Print-based DA; n = 630 2) UC; n = 632
Wilkes, 2013 [42]	General medicine	Multifaceted	<ul style="list-style-type: none"> Interactive web-based Self-administered 	<ul style="list-style-type: none"> Patient: 60 min before consultation; physician: before patient visits Intervention delivery location: n.r.; control: on-site clinic 	n.r.	Web-based physician education + web-based patient activation + access to CDC brochure; n = 19 waiting areas, 41 physicians	1) Web-based physician education + access to CDC brochure; n = 19 waiting areas, 246 patients, 41 physicians 2) UC practice: CDC educational brochures; n = 17 waiting areas, 353 patients, 43 physicians
Williams, 2013 [43]	Multidisciplinary (hospital and specialised)	Single	<ul style="list-style-type: none"> Print-based Self-administered 	<ul style="list-style-type: none"> Before screening exam on-site clinic or home 	Yes	DA-Home CDC-adapted booklet; n = 138	1) Fact sheet DA-Clinic NCI booklet; n = 134 2) UC at home; n = 137 3) UC at clinic; n = 134
Landrey, 2013 [44]	General medicine	Single	<ul style="list-style-type: none"> Print-based flyer Self-administered 	<ul style="list-style-type: none"> 1 week before annual health maintenance visit Home 	Yes	Flyer with patient encouragement to talk with providers; n = 145	1) UC with no flyer; n = 158
Sheridan, 2012 [45]	General medicine	Multifaceted vs single	<ul style="list-style-type: none"> Video, coaching sessions and counselling and print-based brochure Physicians or self-administered 	<ul style="list-style-type: none"> 1 hour before consultation On-site clinic (private room) 	Unclear/n.r.	Video-based DA + coaching session + supplemental brochure; n = 60	1) Educational video on highway safety; n = 70
Lepore, 2012 [46]	Population-based	Multifaceted	<ul style="list-style-type: none"> Print-based and telephone Interventionists (graduate students with training in public health and health education) and trained graduate-level health educators 	<ul style="list-style-type: none"> Health insurance or at consultation Home 	Yes	Telephone tailored education sessions + low literacy educational pamphlet; n = 244	1) Attention control: telephone tailored education sessions (fruit and vegetable consumption) + educational pamphlet; n = 246
Myers, 2011 [47]	General medicine	Multifaceted	<ul style="list-style-type: none"> Face-to-face counselling sessions Physicians 	<ul style="list-style-type: none"> At consultation visit for non-acute care On-site clinic 	Unclear/n.r.	Enhanced intervention: structured decision counselling session + generic note in medical chart to prompt discussions with physician + informational brochure; n = 156	1) SC: practice quality assessment survey + generic note in medical chart to prompt discussions + informational brochure; n = 157
Evans, 2010 [48]	General medicine	Single	<ul style="list-style-type: none"> Web-based and text (from web) Self-administered 	<ul style="list-style-type: none"> Not tied to consultation (men identified from patients' registry), but delivered before patients' filling out questionnaire Home or other settings 	Unclear/n.r.	Web-based DA Prosdex interactive program; n = 129	1) Paper-based DA Prosdex; n = 126 2) Control questionnaire; n = 127 3) Control no questionnaire (received nothing); n = 132
Stamatiou, 2008 [49]	Multidisciplinary (hospital and specialised)	Single vs multifaceted	<ul style="list-style-type: none"> Print-based illustrated leaflet Self-administered 	<ul style="list-style-type: none"> During pre-test interview and before consultation On-site clinic or home 	Yes	Pre-test interview with physician + illustrated educational leaflet; n = 548	1) UC: pre-test interview with physician and physician's advice; n = 587
Frosch, 2008 [50]	General medicine	Multifaceted vs single	<ul style="list-style-type: none"> Internet-based Self-administered 	<ul style="list-style-type: none"> 2–3 weeks before health appraisal consultation Anywhere (internet): home or work 	Unclear/n.r.	Web-based traditional DA; n = 155	1) Web-based CDTM; n = 153 2) Web-based TDA + web-based CDTM (n = 152); n = 152 3) Web links to screening sites from ACS and CDC; n = 151

First author, publication year [reference]	Healthcare context	Strategy	Format and delivery mode	Delivery time and location	Health literacy or numeracy	Intervention and randomised patients, n	Comparator(s) and randomised patients, n
Volk, 2008 [51]	General medicine	Single	<ul style="list-style-type: none"> • Video (interactive edutainment), audio booklet • For subjects at the low-literacy site: RA read material • For subjects at the high-literacy sites: self-administered • RA were available to assist men with using the aids 	<ul style="list-style-type: none"> • Before consultation • On-site clinic 	Yes	Edutainment: interactive and entertainment multimedia DA with medical information combined with storyline; n = 224	1) Audio booklet without interactivity and entertainment factors; n = 226
Krist, 2007 [52, 53] (Woolf, 2005)	General medicine	Single	<ul style="list-style-type: none"> • Internet link to web-based or paper-based • Self-administered 	<ul style="list-style-type: none"> • Within 2 weeks of consultation • Home 	Unclear/n.r.	Web-based DA; n = 226	1) Pamphlet (paper version of web-based) DA; n = 196 2) UC with no pre-visit educational material; n = 75
Kripalani, 2007 [54]	Hospital	Single	<ul style="list-style-type: none"> • Print-based pamphlets in high detail or low detail • Self-administered 	<ul style="list-style-type: none"> • Before consultation • On-site clinic (waiting room) 	Yes	High-detail patient educational pamphlet to promote SDM; n = 101	1) Low-detail "Talk to your doctor" Cue hand-out; n = 101 2) Attention control: pictured traditional food pyramid; n = 101
Partin, 2006 [55, 56] (Partin, 2004)	General medicine	Single	<ul style="list-style-type: none"> • Video or print-based pamphlet • Self-administered 	<ul style="list-style-type: none"> • Within 2 weeks before consultation • Home 	Yes	Video "The PSA Decision: What YOU Need to Know" by the FIMDM; n = 384	1) Pamphlet developed for study; n = 384 2) UC and whatever decision-making support provided in routine appointments; n = 384
Watson, 2006 [57]	General medicine	Multifaceted vs single	<ul style="list-style-type: none"> • Print-based • Self-administered 	<ul style="list-style-type: none"> • Not tied to consultation, but delivered at same time as questionnaire • Home 	Yes	Brief patient DA leaflet + questionnaire; n = 980	1) Control questionnaire only; n = 980
Myers, 2005 [58]	General medicine	Multifaceted vs single	<ul style="list-style-type: none"> • Print-based booklet and face-to-face educational sessions • Self-administered or trained health educator 	<ul style="list-style-type: none"> • Before consultation • On-site clinic or home 	Yes	Enhanced intervention: informational booklet + decision education session by telephone; n = 121	1) SC: informational booklet; n = 121
Gatellari, 2003 [59]	General medicine	Single	<ul style="list-style-type: none"> • Print-based booklet and pamphlet • Self-administered 	<ul style="list-style-type: none"> • Before consultation • On-site clinic 	Yes	Evidence-based booklet; n = 126	1) Pamphlet by the Australian government; n = 122
Frosch, 2003 [60, 61] (Frosch, 2001)	General medicine	Single	<ul style="list-style-type: none"> • Videotape DA and web-version of videotape DA • Self-administered 	<ul style="list-style-type: none"> • Before (30 min or until time/date of) health appraisal consultation • On-site clinic (videotape) or anywhere (web-based) 	Unclear/n.r.	Web-based DA; n = 114	1) Video DA; n = 112
Volk, 2003 [62, 63] (Volk, 1999)	General medicine	Multifaceted (video and brochure)	<ul style="list-style-type: none"> • Video or print-based (brochure) • Self-administered 	<ul style="list-style-type: none"> • Before consultation • on-site clinic (video) or home (brochure) 	Yes	Educational video by the FIMDM + accompanying brochure; n = 80	1) No intervention before visit + brochure after 2 week follow-up assessment; n = 80
Schapira, 2000 [64]	General medicine	Multifaceted vs single	<ul style="list-style-type: none"> • Print-based pamphlet • Self-administered and RA present and available to answer questions 	<ul style="list-style-type: none"> • 2 weeks before consultation • On site clinic 	Yes	Pamphlet DA about prostate cancer screening and treatment + educational information included in comparator pamphlet; n = 122	1) Basic information pamphlet; n = 135
Davison, 1999 [65]	General medicine	Multifaceted vs single	<ul style="list-style-type: none"> • Verbal and written (information) • Physician (intervention) or investigator (control) 	<ul style="list-style-type: none"> • Before periodic health examination • On-site clinic 	Unclear/n.r.	Verbal and written information with encouragement to discuss with physician and to participate decision-making; n = 50	1) Attention control: discussion about general issues; n = 50
Wolf, 1998 [66, 67] (Wolf, 1996)	General medicine	Single	<ul style="list-style-type: none"> • Written (information) • RA (read aloud the interventions) 	<ul style="list-style-type: none"> • Before consultation • On-site clinic 	Yes	Scripted overview of PSA screening; n = 103	1) Brief control message about PSA availability; n = 102

First author, publication year [reference]	Healthcare context	Strategy	Format and delivery mode	Delivery time and location	Health literacy or numeracy	Intervention and randomised patients, n	Comparator(s) and randomised patients, n
Treatment							
Chabrera, 2015 [68]	Multidisciplinary (hospital and specialised)	Single	<ul style="list-style-type: none"> • Print-based booklet • Self-administered 	<ul style="list-style-type: none"> • After first consultation • Take-home with on-site explanation (by physicians and nurses) 	Unclear/n.r.	Printed booklet DA with information, values clarification exercise and interview preparation material for consultation; n = 73	1) Standard information; n = 74
Berry, 2013 [69–71] (Berry, 2012; Bosco, 2012)	Multidisciplinary (hospital and specialised)	Single	<ul style="list-style-type: none"> • Computer (touch-screen in clinic or computer at home), text, print-based, video • Self-administered 	<ul style="list-style-type: none"> • Before consultation • On-site clinic or home 	Yes	Tailored internet aid; n = 266	1) Website links to established information about prostate cancer; n = 228
Hacking, 2013 [72]	Hospital	Single	<ul style="list-style-type: none"> • Face-to-face communication-interaction • RA 	<ul style="list-style-type: none"> • Before consultation • Face-to-face meeting or telephone 	Yes	Coaching DA: preparing for tailored personal consultation plan; n = 63	1) UC pathway with discussion of treatment options with specialists; n = 60
van Tol-Geerdink, 2013 [73]	Hospital	Single	<ul style="list-style-type: none"> • Face-to-face semi-structured interview and written information • Researcher 	<ul style="list-style-type: none"> • Before second consultation (when participants elaborated on treatment choice with urologist) • On-site clinic or home 	Yes	Semi-structured interview consultation DA to provide information + discussion of treatment choice with specialists; n = 163	1) UC with discussion of treatment options with specialists; n = 77
Huang, 2014 [74–76] (Auvinen, 2004; Auvinen, 2001)	Hospital	Multifaceted vs single	<ul style="list-style-type: none"> • Verbal and written (structured information) • Physicians in both groups 	<ul style="list-style-type: none"> • During consultation • On-site clinic 	Unclear/n.r.	Enhanced participation: patient-defined role in decision-making actively emphasised and discussions with urologist + structured information on treatment options; n = 104	1) SC protocols; n = 106
Feldman-Stewart, 2012 [77–79] (Feldman-Stewart, 2004; Feldman-Stewart, 2001)	Specialised (cancer)	Multifaceted vs single	<ul style="list-style-type: none"> • Computer program and interview • Self-administered and interview by RA (available to answer questions about using DA computer program) 	<ul style="list-style-type: none"> • Between initial (doctor presents the treatment options) and second (~1 week later when treatment decision is made) consultation • On-site clinic 	Unclear/n.r.	Computer DA interview with well-structured information and Value Clarification Exercises; n = 81	1) Computer DA interview with well-structured information and general questions; n = 75
Taylor, 2010 [80]	Multidisciplinary (hospital and population-based)	Multifaceted	<ul style="list-style-type: none"> • CD-ROM and interactive tools • Self-administered (home) or research staff (at study research offices) 	<ul style="list-style-type: none"> • After first (baseline) telephone interview (material mailed sixteen days (median) after biopsy) but before (1 mo) follow-up telephone interview • On-site study office or home 	n.r.	Information CD + interactive decision tools; n = 66	1) Information CD; n = 66
Mishel, 2009 [81]	Multidisciplinary (hospital and specialised)	Multifaceted vs single	<ul style="list-style-type: none"> • Video DVD, booklet and telephone calls • Self-administered and telephone calls by nurse (trained in the study intervention) 	<ul style="list-style-type: none"> • 10 days to 2 weeks before consultation • Home 	Yes	TS: DVD + booklet + 4 telephone calls to patients and primary support person; n = 89	1) TD: DVD + booklet + 4 telephone calls to patients only; n = 93 2) UC: handout on staying healthy during treatment; n = 74
Hack, 2007 [82]	Specialised (cancer)	Single	<ul style="list-style-type: none"> • Audiotape recording • Clinical research nurse 	<ul style="list-style-type: none"> • During consultation (recording of clinical encounter) • on-site clinic 	Unclear/n.r.	Audiotape: audio recording of clinical encounter; n = 214	1) Consultation not audiotaped; n = 211
Davison, 2007 [83]	Hospital care	Multifaceted	<ul style="list-style-type: none"> • Written information • Videotape, telephone, research nurse 	<ul style="list-style-type: none"> • Within 10 days of being referred and before consultation • On-site (patient-education) centre 	Unclear/n.r.	Individualised information printout based on preferences and disease + written information package + telephone call weeks later + encouragement to bring significant others to appointment; n = 162	1) Generic information videotape + written information package + telephone call four weeks later + encouragement to bring significant others to appointment; n = 162
Feldman-Stewart, 2006 [84]	Specialised (Cancer)	Single	<ul style="list-style-type: none"> • Print-based booklet • Self-administered 	<ul style="list-style-type: none"> • Before and after the evaluation questionnaires; after first consultation (consent), but before (reading the intervention) the AFTER 	Yes	CCE information booklet; n = 152	1) Standard information booklet developed by AstraZeneca routinely provided to patients; n = 156

First author, publication year [reference]	Healthcare context	Strategy	Format and delivery mode	Delivery time and location	Health literacy or numeracy	Intervention and randomised patients, n	Comparator(s) and randomised patients, n
				questionnaire • Home			
Davison, 1997 [85]	General medicine	Multifaceted (verbal and written)	• Booklet, written and verbal • Research staff and nurse gave interviews in preparation for consultation and helped patients in the intervention group	• Before treatment consultation • On-site clinic	Unclear/n.r.	Empowerment intervention - interview preparing for consultation; n = 30	1) Written information package; n = 30
Screening and treatment							
Wilt, 2001 [86]	General medicine	Single	• Print-based pamphlet • Self-administered	• 7–10 days before consultation • Home	Yes	Question and answer printed sheets; n = 275	1) UC alone; n = 275

RA = Research Assistant; n.r. = not reported. DESI = DEcision Support Intervention; SMA = shared medical appointment; NCI = National Cancer Institute; CDC = Centers for Disease Control and Prevention; ACS = American Cancer Society; TDA = traditional DA; CDTM = Chronic Disease Trajectory Model; FIMDM = Foundation for Informed Medical Decision Making; TD = treatment direct; TS = treatment supplemented; CCE = Cancer Care and Epidemiology Unit from Cancer Research Institute; UC = usual care; SC = standard care intervention.

be explicitly termed as such. Informed decision-making is the most frequently used term in the literature and it could be either a stand-alone strategy to facilitate SDM, or one component of multi-faceted interventions. SDM could also be measured as a process (e.g., recording consultations) or can be conceptualised as an outcome.

The quality of implementation of SDM interventions varied widely among studies. In most, the interventions were consistent in providing information, and the majority (n = 28) intended to involve deliberation to some degree. In fact, interventions were mostly delivered before consultations, interviews, evaluations or questionnaires as an attempt to empower patients. However, only 38.9% (n = 14) met the key criteria for SDM as proposed by Charles et al. [35]. Interestingly, half of the treatment studies, compared with nearly 35% of the screening studies, achieved the three key SDM features.

Given the prevalence of prostate cancer, that SDM is guideline recommended and viewed as the fundamental component of all interactions between patients and healthcare providers, it is surprising to find only a small number of studies on the effects of SDM for prostate cancer, especially treatment. However, nearly half (44.5%) of the included studies were published from 2010 onwards, which might indicate a growing area of research. In addition, most (55.5%) studies considered decision-making within the context of primary care by general practitioners, and only a few evaluated decision-making in the context of specialised care by urologists or oncologists. Moreover, the study interventions were developed to target mostly patients (88.9%), rarely involving the patients' significant others (e.g., family members, carers) despite recommendations that views and participation from others in decision-making may lead to more efficient and effective healthcare [29, 88].

Our review confirms an increase in the development of SDM interventions for prostate cancer. It also confirms the lack of both consensus on the definition of SDM and guidance for SDM implementation in routine practice. Makoul et al. [14] identified a range of 31 different SDM definitions and, as noted in our review, their recommendations for a single and more integrative concept of SDM are yet to be followed. Future research should consider that this variability might make comparison across studies difficult, and that consistent reporting of interventions and their compo-

nents could allow better estimation of SDM implementation. Involving others (e.g., patients' carers or relatives) in the process of decision-making might affect patient outcomes and should be considered in further research. Nevertheless, our results merit further evaluation of their impact on patient outcomes.

Strengths and limitations

To our knowledge, this is the first systematic review about SDM implementation for both screening and treatment for prostate cancer. As such, this review focused on assessing and describing the reported SDM interventions and their implementation in clinical practice based on the SDM model. Given the lack of a single SDM definition, we considered the diversity in the type of interventions that would be compatible with SDM. Various reviews have focused on decision aids. We used a broad definition of SDM interventions and did not limit our search strategy exclusively to the term “shared decision-making” or “decision aids”. We used a range of search terms relevant to decision-making, including SDM and decision aids. We applied broad inclusion criteria at the screening stage and full-text evaluation, and included studies regardless of whether a specific decision was promoted. Our review also covered international literature with no restriction to countries or type of healthcare provider. We included literature published in English only, and academic databases were searched up to March 2015. However, we made considerable efforts to identify all relevant studies by comprehensively searching both peer-reviewed and grey (accessed: February–August 2016) literature in twelve sources. We also contacted authors (2015–2017) of abstracts for which full texts were not available, increasing the chance of identifying more literature that is contemporary. Our work thus benefited from the response of authors, which led to the identification of more studies and thus more complete data were considered for eligibility. Moreover, our method for evaluating the implementation of SDM confirmed that research gaps in the conceptualisation of SDM continue despite previous recommendations [14]. We used the SDM model by Charles et al. [35] because it represents only one SDM concept, and it is the most prominent [14] approach to viewing SDM compared with other models of decision-making. Our review thus presents the elements and key features of SDM

Table 4: Elements and key features of decision-making interventions for prostate cancer screening and treatment.

First author, publication year [reference]	Healthcare context	Operational framework	Elements for fostering SDM			Key features of SDM implementation			
			Study aim to assess SDM	Intervention fostering SDM	bi-directional interaction	a. Information exchange (physician ↔ patients)	b. Deliberation (physician ↔ patients)	c. Implementation (physician ↔ patients)	Class, [a-b-c]
Screening									
Lewis, 2015 [37]	General medicine	Unclear/n.r.	Yes	Yes	Yes	Yes	Yes	Unclear	2, [1-1-?]
Tomko, 2015 [38–41] (Starosta, 2015; Tomko, 2015; Taylor, 2013)	Multidisciplinary (hospital and specialised)	Yes	No	Yes	Unclear	Unclear	Unclear	Unclear	3, [?-?-?]
Wilkes, 2013 [42]	General medicine	Unclear/n.r.	Yes	Yes	Yes	Yes	Yes	Yes	1, [1-1-1]
Williams, 2013 [43]	Multidisciplinary (hospital and specialised)	Unclear/n.r.	No	Yes	Yes	Yes	Yes	No	2, [1-1-0]
Landrey, 2013 [44]	General medicine	Yes	Yes	Yes	Yes	Yes	Yes	Yes	1, [1-1-1]
Sheridan, 2012 [45]	General medicine	Yes	Yes	Yes	Yes	Yes	Yes	Yes	1, [1-1-1]
Lepore, 2012 [46]	Population-based	Yes	Yes	Yes	Yes	Yes	Yes	Unclear	2, [1-1-?]
Myers, 2011 [47]	General medicine	Yes	Yes	Yes	Yes	Yes	Yes	Yes	1, [1-1-1]
Evans, 2010 [48]	General medicine	Yes	No	Yes	No	No	No	No	4, [0-0-0]
Stamatiou, 2008 [49]	Multidisciplinary (hospital and specialised)	Yes	Yes	Yes	Yes	Yes	Yes	Unclear	2, [1-1-?]
Frosch, 2008 [50]	General medicine	Unclear/n.r.	No	Yes	Yes	Yes	Yes	Unclear	2, [1-1-?]
Volk, 2008 [51]	General medicine	Yes	No	Yes	Yes	Yes	Yes	Unclear	2, [1-1-?]
Krist, 2007 [52, 53] (Woolf, 2005)	General medicine	Yes	Yes	Yes	Yes	Yes	Yes	Yes	1, [1-1-1]
Kripalani, 2007 [54]	Hospital	Unclear/n.r.	Yes	Yes	Yes	Yes	Yes	Unclear	2, [1-1-?]
Partin, 2006 [55, 56] (Partin, 2004)	General medicine	Yes	Yes	Yes	Yes	Yes	Yes	No	2, [1-1-0]
Watson, 2006 [57]	General medicine	Yes	No	Yes	No	No	No	No	4, [0-0-0]
Myers, 2005 [58]	General medicine	Yes	Yes	Yes	Yes	Yes	Yes	Yes	1, [1-1-1]
Gatellari, 2003 [59]	General medicine	Unclear/n.r.	Yes	Yes	Yes	Yes	Yes	Yes	1, [1-1-1]
Frosch, 2003 [60, 61] (Frosch, 2001)	General medicine	Unclear/n.r.	Yes	Yes	Yes	Yes	Yes	No	2, [1-1-0]
Volk, 2003 [62, 63] (Volk, 1999)	General medicine	Yes	Yes	Yes	Yes	Yes	Yes	No	2, [1-1-0]
Schapira, 2000 [64]	General medicine	Yes	Yes	Yes	Yes	Unclear	Unclear	Unclear	3, [?-?-?]
Davison, 1999 [65]	General medicine	Unclear/n.r.	Yes	Yes	Yes	Yes	Yes	Yes	1, [1-1-1]
Wolf, 1998 [66, 67] (Wolf, 1996)	General medicine	Yes	No	No	Yes	No	No	No	4, [0-0-0]
Treatment									
Chabrera, 2015 [68]	Multidisciplinary (hospital and specialised)	Yes	No	Yes	Unclear	Unclear	Unclear	Unclear	3, [?-?-?]
Berry, 2013 [69–71] (Berry, 2012; Bosco, 2012)	Multidisciplinary (hospital and specialised)	Yes	No	Yes	Yes	Yes	Yes	No	2, [1-1-0]
Hacking, 2013 [72]	Hospital	Yes	Yes	Yes	Yes	Yes	Yes	Unclear	2, [1-1-?]
van Tol-Geerdink, 2013 [73]	Hospital	Yes	No	Yes	Yes	Yes	Yes	Unclear	2, [1-1-?]

First author, publication year [reference]	Healthcare context	Operational framework	Elements for fostering SDM			Key features of SDM implementation			
			Study aim to assess SDM	Intervention fostering SDM	bi-directional interaction	a. Information exchange (physician ↔ patients)	b. Deliberation (physician ↔ patients)	c. Implementation (physician ↔ patients)	Class, [a-b-c]
Huang, 2014 [74–76] (Auvinen, 2004; Auvinen, 2001)	Hospital	Unclear/n.r.	Yes	Yes	Yes	Yes	Yes	Yes	1, [1-1-1]
Feldman-Stewart, 2012 [77–79] (Feldman-Stewart, 2004; Feldman-Stewart, 2001)	Specialised (cancer)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	1, [1-1-1]
Taylor, 2010 [80]	Multidisciplinary (hospital and population-based)	Unclear/n.r.	No	Yes	No	No	No	No	4, [0-0-0]
Mishel, 2009 [81]	Multidisciplinary (hospital and specialised)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	1, [1-1-1]
Hack, 2007 [82]	Specialised (cancer)	Unclear/n.r.	Yes	Yes	Yes	Yes	Yes	Yes	1, [1-1-1]
Davison, 2007 [83]	Hospital care	Yes	Yes	Yes	Yes	Yes	Yes	Yes	1, [1-1-1]
Feldman-Stewart, 2006 [84]	Specialised (cancer)	Unclear/n.r.	Yes	Yes	Yes	No	No	No	4, [0-0-0]
Davison, 1997 [85]	General medicine	Yes	Yes	Yes	Yes	Yes	Yes	Yes	1, [1-1-1]
Screening and treatment									
Wilt, 2001 [86]	General medicine	Unclear/n.r.	Yes	Yes	Yes	Yes	Yes	Unclear	2, [1-1-?]

n.r. = not reported. General medicine = general, internal, family and/or community practice clinics, preventive medicine, Veterans' affair or primary practice clinics. Class: 1 = SDM, 2 = partial SDM, 3 = unclear deliberation, 4 = no SDM: no deliberation. Each SDM key feature [a-b-c] was coded as 1 = criteria met, 0 = criteria not met, or unclear (?) = judgement could not be made owing to unclear or lack of reporting (see [table S4](#) in appendix 1).

interventions and provides an overview of the extent of SDM implementation for prostate cancer.

Our review was limited by the quality of reporting of intervention details, which made the verification of SDM criteria difficult at times. Thus we cannot exclude the possibility that we underestimated SDM implementation. Many studies were published within the last decade, but the use of frameworks was lacking in nearly a third of them.

Conclusions

There is a significant variation in the components of SDM interventions for prostate cancer screening and treatment. Only 39% of the studies contained the SDM intervention components suggested in the SDM model, and interventions were implemented mostly within the context of primary care. These results merit further evaluation on patient outcomes. There might be strong ethical, medical and interpersonal reasons to recommend SDM. However, to date there seems to be uncertainty about the SDM concept, intervention content, and how to implement SDM in practice. A standardised SDM definition and guidance for SDM implementation in practice that is feasible for several clinical settings are needed.

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Appendix 1: Supplementary tables

The supplementary tables are available in a separate file for downloading at: <https://smw.ch/en/article/doi/smw.2018.14584/>

Table S1: PRISMA checklist.

Table S2: Search strategy for OVID Medline.

Table S3: Models of shared decision-making.

Table S4: Method for assessing the key features of SDM implementation.

Table S5: Characteristics of study, population and interventions of 36 randomised clinical trials in review.

Appendix

Supplementary Tables

Table S1. PRISMA checklist.

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	1-2
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	2
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	2
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	2
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	2
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Table S2 of this appendix

Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	2
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	2
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	2
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	na
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	2
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	2-3
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	na
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	na
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	3
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	3
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	na
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	3-5
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	na
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	na
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	na

DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	5
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	11
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	11-12
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	No external funding
<p><i>From:</i> Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097</p> <p>For more information, visit: www.prisma-statement.org</p>			

Table S2. Search strategy for OVID Medline.

Item	Searches
1	exp Decision Making/ or Decision Making, Organizational/ or Decision Trees/ or Decision Making/ or Decision Support Techniques/ or Decision Support Systems, Clinical/ or Decision Making, Computer-Assisted/ or exp Computer-Assisted Instruction/ or exp Patient Participation/ or exp Professional-Patient Relations/ or exp "Attitude of Health Personnel"/ or Counseling/ or exp Health Communication/
2	exp Informed Consent/
3	(choice behavior or decision making or shared decision making).mp,tw.
4	(informed adj3 (consent or choice* or decision*)).mp,tw.
5	((decision* or decid*) adj4 (support* or aid* or tool* or instrument* or technolog* or technique* or system* or program* or algorithm* or process* or method* or intervention* or material*)).mp,tw.
6	(decision adj3 (board* or guide* or counseling)).mp,tw.
7	(computer* adj4 decision making).mp.
8	(patient adj3 (participation or involvement or cent#d care)).mp,tw.
9	((risk communication or risk assessment or risk information) adj4 (tool* or method*)).mp,tw.
10	interact* health communication*.mp,tw.
11	(interact* adj (internet or online or graphic* or booklet*)).mp,tw.
12	(interact* adj4 tool*).mp,tw.
13	((interact* or evidence based) adj3 (risk information or risk communication or risk presentation or risk graphic*)).mp,tw.
14	adaptive conjoint analys#s.mptw.
15	or/1-14
16	(Prostat* adj3 (Neoplasm* or Cancer or tumo?r* or carcinoma)).mp,tw.
17	exp Prostatic Neoplasms/
18	16 or 17
19	15 and 18
20	(letter or letter\$ or editorial or historical article or anecdote or commentary or note or case report\$ or case study).pt,sh.
21	(animals not humans).sh.
22	20 or 21
23	19 not 22
24	exp Randomized Controlled Trial/ or exp clinical trial/
25	randomized controlled trial.pt.

26	randomized controlled trial.sh.
27	controlled clinical trial.pt.
28	random allocation.sh.
29	double blind method.sh.
30	single blind method.sh.
31	or/24-30
32	31 not 22
33	exp clinical trial/ or exp Clinical Trials as Topic/
34	clinical trial.pt.
35	((singl\$ or doubl\$ or trebl\$ or trpl\$) adj25 (blind\$ or mask\$)).ti,ab.
36	(clin\$ adj25 trial\$).ti,ab.
37	(random\$ or placebo\$).ti,ab.
38	(PLACEBO or RESEARCH DESIGN).sh.
39	or/33-38
40	39 not 22
41	40 not 32
42	exp EVALUATION STUDIES/
43	(comparative study or follow up studies or prospective studies).sh.
44	(control\$ or prospectiv\$ or volunteer\$).ti,ab.
45	or/42-44
46	45 not 22
47	46 not (32 or 41)
48	23 and (32 or 41 or 47)

Table S3. Models of shared decision-making.

MODEL	Paternalistic (traditional)	Shared decision-making	Informed decision	Physician as perfect agent
Role				
Healthcare provider (HCP)	Active: transfers selected information to patient; makes decisions about the therapy s/he considers best for the patient without obtaining personal information or involving the patient in decision-making process.	Active: shares information and therapy options, their benefits and harms with patient; discusses preferences and values with patient; recommends therapy alternatives; decides on the choice of therapy in consensus with the patient.	Passive: transfers information and treatment options with benefits and harms to patient; withholds recommendations; makes no decisions.	Active: patient's preferences are transferred to HCP who has the knowledge to identify the treatment options most desirable from patient' perspective and recommends such to the patient.
Patient	Passive: accepts professional authority and agrees to therapy proposed by professional.	Active: shares information and knowledge; receives information; makes own judgement about options, harms and benefits; discusses values and preferences with HCP; decides on the choice of therapy in consensus with HCP.	Active: receives information; makes own judgement on options, based on harms, benefits, values and preferences; chooses freely between options without HCP intervention; decides on therapy alone.	Active: receives all information about the treatment and accepts or rejects it according to his/her expectations.
		Requires the sharing of treatment preferences and decisions by both HCP and patients	Preferences of the HCP are excluded	Relies on the HCP determining patient preferences and including these in the decision. HCP may not accurately gauge patients' preferences and thus patients' perspective may not be involved in the decision
Process flow				
Interaction	Uni-directional:	Bi-directional:	Uni-directional:	Uni-directional:
Information-exchange	HCP → patient	HCP ↔ patient	HCP → patient	HCP → patient
type of information	medical, legal requirement	medical and personal, anything relevant for decision making	medical, anything relevant and enough to enable patient to make a treatment decision	
Deliberation	at least one HCP	HCP and patient +/- patient care-related parties (significant others, legal guardian, relatives and/or caregivers or other clinicians)	patient (+/- patient care-related parties: significant others, legal guardian, relatives and/or caregivers or other clinicians)	HCP
Decision implementation	HCP	HCP and patient	patient	HCP
Adapted from Charles <i>et. al.</i> [24, 35].				

Table S4. Method for assessing the key features of SDM implementation.

Extent of SDM	a. information exchange (physician ↔ patients)	b. deliberation (physician ↔ patients)	c. implementation (physician ↔ patients)	Classification
1. SDM	1	1	1	[1-1-1]
2. Partial SDM	0	1	1	[0-1-1]
	1	1	0	[1-1-0]
	?	1	1	[?-1-1]
	1	1	?	[1-1-?]
3. Unclear deliberation	?	?	?	[?-?-?]
	?	?	1	[?-?-1]
	1	?	?	[1-?-?]
	1	?	1	[1-?-1]
4. No-SDM: no deliberation				
No-SDM: unidirectional	0	0	0	[0-0-0]
No-SDM: isolated information	1	0	0	[1-0-0]
No-SDM: no deliberation	1	0	1	[1-0-1]
No-SDM: isolated decision	0	0	1	[0-0-1]
Key features based on Charles <i>et al</i> [24, 35]. 1 = criteria met, 0 = criteria not met, unclear (?) = judgement could not be made due to unclear or lack of reporting.				

Table S5. Characteristics of study, population and interventions of 36 RCTs in review.

First author, publication year	Country, study design & period of conduct	Setting and facilities, n	Inclusion criteria	Exclusion criteria	Intervention arm	Control arm	Operational framework
					Intervention & randomised patients, N	Comparator & randomised patients, N	
SCREENING							
Lewis, 2015 [37]	USA RCT, parallel Feb 2011 to Dec 2012 (intervention) Funding: non-profit	Primary care practices, 7 Primary care academic general internal medicine practice, 1	Men 50 to 75 years old, selected from the pool of eligible patients in the electronic medical records, without diagnosis of prostate cancer who had not had a PSA test in the past 10 months and who had not seen their primary care physician in the last 3 months	n.r.	1) DESI group: 31 min PSA DVD DESI (decision Support Interventions) (developed by the Informed Medical Decisions Foundation); N=831	1) SMA group: invitation to participate in a shared (group) medical appointment (SMA) to watch and discuss the PSA DVD DESI with a mid-level healthcare provider and other patients; N=840 2) DESI + SMA group: 31 min PSA DVD DESI + invitation to participate in a SMA; N=828 3) No additional intervention material; N=828	Unclear/n.r.
Tomko, 2015 [38-41] (Starosta, 2015; Tomko, 2015; Taylor, 2013)	USA RCT, parallel Oct 2007 to Jan 2010 (recruitment) Funding: non-profit	University hospital, 1 Hospital centre, 1 Medstar physician partners, 1	Men 45 to 70 years old, no prior history of prostate cancer, English speaking, with ability to provide informed consent, independent living, having had an outpatient visit in the last 24 months	Men with history of prostate cancer, nursing home residents	1) 8th grade reading level web-based DA with six informational sections, six video testimonials, and a values clarification tool; N=631	1) 8th grade reading level print-based DA with six informational sections, six video testimonials, and a values clarification tool; N=630 2) Usual care; N=632	Ottawa Decision Support Framework (ODSF)
Wilkes, 2013 [42]	USA RCT, cluster May 2007 to Dec 2008 Funding: non-profit	Primary care networks academic-medical-centre affiliated, 2 Staff model health maintenance organisations, 2 Medical group practice network, 1	Men 55 to 65 years old, patients with no serious comorbidity (including any known cancer) and English speakers; physicians consented to participate in educational activities and to help recruit patients	n.r.	1) MD-Ed+A: 30-min interactive web-based educational program + 30-min web-based patient activation + access to CDC brochure in waiting area; 19 waiting areas, 113 patients, 36 physicians	1) MD-Ed: 30-min interactive web-based educational program + access to CDC brochure in waiting area (19 waiting areas; 41 physicians with 246 patients); 19 waiting areas, 246 patients, 41 physicians 2) Usual care practice: CDC educational brochures on prostate cancer in waiting areas (17 waiting areas; 43 physicians with 353 patients); 17 waiting areas, 353 patients, 43 physicians	Unclear/n.r.

Williams, 2013 [43]	USA RCT, parallel Period, n.r. Funding: non-profit	University medical centre, 1 University cancer centre, 1	Men 40 to 70 years old, who had pre-registered for screening at least 5 days in advance, had no history of prostate cancer and English- speakers	Walk-in patients	1) 20-min 8th-grade reading level DA-Home booklet CDC-adapted (mailed 5–10 days before the scheduled screening date), 24- page colour, titled "prostate cancer Screening: Making an Informed Decision"; N=138	1) 5-min, 3-page fact sheet DA- Clinic booklet NCI (National Cancer Institute) (distributed at the screening appointment), titled "Questions and Answers About the Prostate Specific Antigen Test"; N=134 2) Usual care at home (information mailed to participants' homes 5–10 days before screening date; contained little information about the prostate, treatment options, and had no values clarification tool); N=137 3) Usual care at clinic (information was distributed at the screening appointment; contained little information about the prostate, treatment options, and had no values clarification tool); N=134	Unclear/n.r.
Landrey, 2013 [44]	USA RCT, parallel Oct 2009 to Aug 2010 Funding: non-profit	General internal medicine practices - University-Hospital affiliated, 2	Men 50 to 74 years old, patients scheduled to have an annual health maintenance exam between October 2009 and August 2010	Men with PSA test within the past 12 months, had a history of prostate cancer, or any other diagnosis of cancer, terminal illness or dementia	1) Flyer (mailed), 4th grade level (about the PSA test, prostate cancer, risks and benefits of screening) with patient encouragement to talk with their providers (about whether a PSA test was appropriate for them); N=145	1) Usual care with no flyer; N=158	Patient-Centred Approach
Sheridan, 2012 [45]	USA RCT, parallel Mar 2005 to Apr 2006 Funding: non-profit	Academic practice, 2 Community practice, 2	Men 40 to 80 years old, with no prior history of prostate cancer, seen in the practice for at least 1 year; physicians also were invited and agreed to participate	Men presenting for an acute medical visit, evidence of serious medical illness (e.g. Intensive care hospitalization within the last 6 months, more than 2 hospitalizations in the last 6 months)	1) 12-min video-based DA + 8-min coaching session + supplemental brochure; N=60	1) Educational video on highway safety; N=70	Shared Participation Approach to Decision-Making
Lepore, 2012 [46]	USA RCT, parallel Period, n.r. Funding: non-profit	Insurance company for beneficiaries healthcare workers' union, 1	Men 45 to 70 years old, of Black African descent, accessible by telephone, have a primary care physician	Men with prostate cancer test in the past 12 months before enrollment and who had a history of prostate cancer	1) 2(max.)-telephone tailored education sessions (initial call: 20- min; follow-up call: 5-min) within 1 month (median: 1 week) about prostate cancer testing with key elements (rapport building, values clarification and importance of talking with a physician) + low	1) Attention control: 2(max.)- telephone tailored education sessions (initial call: 20-min; follow-up call: 5-min) within 1 month (median: 1 week) about fruit and vegetable consumption + educational pamphlet (mailed); N=246	Ottawa Decision Support Framework (ODSF)

					literacy educational pamphlet (mailed), titled "Prostate Cancer: Your Life-You Decide" about advantages and disadvantages of prostate cancer testing, prostate cancer risk factors and prostate cancer tests, potential risks and benefits of testing; N=244		
Myers, 2011 [47]	USA RCT, parallel Between 2003 and 2007 Funding: non-profit	Primary care practice, 2	Men 50 to 69 years old, with no history of prostate cancer or benign prostatic hyperplasia, who had no PSA test in past 11 months	n.r.	1) Enhanced intervention: 28-min (mean) structured decision counselling session (about prostate cancer screening) + generic note in medical chart to prompt physician to discuss prostate cancer + 12-page informational brochure (on prostate cancer and screening); N=156	1) Standard intervention: practice quality assessment survey (to match face time of intervention group) + generic note in chart to prompt discussion of prostate cancer screening + 12-page informational brochure (on prostate cancer and screening); N=157	Decision Counselling Theory (as mediated decision support to inform SDM)
Evans, 2010 [48]	UK (South Wales) RCT, parallel Period, n.r. Funding: non-profit	General practices from nine local health board areas, 25	Men 50 to 75 years old, who had not had a PSA test or prostate cancer, and able to use a computer and read English	Men participants who could not read English, those whose general practice records indicated that they had previously had prostate cancer or a PSA test	1) Web-based DA, Prosdex interactive program (online program on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinion, guidance); N=129	1) Paper version of Prosdex text (online DA on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinion, guidance (interactive computer program; summary); N=126 2) Control questionnaire; N=127 3) Control no questionnaire (received nothing); N=132	Informed Decision Making Measure
Stamatiou, 2008 [49]	GRC RCT, parallel Apr 2004 to 2006 Funding: n.r.	Primary care institutions	Men 50 to 86 years old, who had a scheduled primary care appointment for various medical conditions except prostate-related conditions	Appointment for prostate-related conditions	1) Pre-test interview with the physician + additional printed written information in the form of an 554 words double-sided a3 sheet illustrated educational leaflet "prostate cancer screening"; N=548	1) Usual care: pre-test interview with the physician with physician's advice during interview in the examination room; N=587	Patient-Centred Approach
Frosch, 2008 [50]	USA RCT, parallel Mar 2005 to May 2006 (recruitment) Funding: non-profit	Preventive medicine clinic (Kaiser Permanente), 1	Men older than 50 years, who made an appointment at the clinic, and who had broadband Internet access at home or at work, and with informed consent	n.r.	1) Web-based traditional DA (TDA) with information on the clinical problem, outcome options and probabilities, others' opinions; N=155	1) Web-based Chronic Disease Trajectory Model (CDTM) with information on the clinical problem, outcome options and probabilities, others' opinions, and with explicit values clarification (utilities for	Unclear/n.r.

						<p>outcomes associated with prostate cancer); N=153</p> <p>2) Combined TDA and CDTM (n=151) with explicit values clarification (utilities for outcomes associated with prostate cancer); N=152</p> <p>3) Links to public ACS and CDC prostate cancer screening websites; N=151</p>	
Volk, 2008 [51]	<p>USA</p> <p>RCT, parallel</p> <p>Jan 2004 to Feb 2006 (data collection)</p> <p>Funding: non-profit</p>	<p>General medicine clinic from publicly funded hospital (low health literacy site), 1</p> <p>University affiliated family medicine clinic (high health literacy site), 1</p>	<p>Men 40 to 70 years old if African-American, or aged 50 to 70 years if not African-American, who visited clinic for non-acute care, with no history of prostate cancer</p>	n.r.	<p>1) Interactive and entertainment multimedia DA (edutainment DA with tailored computerized program with information options' outcomes, clinical problem, explicit values clarification, others' opinion, guidance); N=224</p>	<p>1) Audio booklet without interactivity and entertainment factors; N=226</p>	<p>Edutainment Decision Aid Model (EDAM)</p>
Krist, 2007 [52, 53] (Woolf, 2005)	<p>USA</p> <p>RCT, parallel</p> <p>Jun 2002 to Jun 2004</p> <p>Funding: non-profit</p>	<p>Suburban family practice centre, 1</p>	<p>Men 50 to 70 years old with a scheduled health maintenance examination</p>	<p>Men with history of prostate cancer, lacked internet access, planned on having blood work before their visit, were enrolled in another prostate cancer investigation, or had already been enrolled in the study</p>	<p>1) Web-based DA (about options' outcomes, clinical problem, outcome probability); N=226</p>	<p>1) 4-page pamphlet (mailed) paper version of web-based DA (with same information as web-based da); N=196</p> <p>2) usual care with no pre-visit educational material; N=75</p>	<p>US Preventive Services Task Force (USPSTF)</p>
Kripalani, 2007 [54]	<p>USA</p> <p>RCT, parallel</p> <p>Jun-Jul 2003 (enrollment)</p> <p>Funding: non-profit</p>	<p>Teaching hospital, 1</p>	<p>Men 45 to 70 years old, waiting for primary care appointment</p>	<p>Men enrolled previously, had history of prostate cancer as determined by a focused review of the patient's electronic medical record, in police custody, arrived ill on a stretcher, not scheduled to see a primary care provider (i.e. Nurse-only visits, medical student appointments, and refill pickups were excluded) for a full visit, not fluent in English on face-to-face screening, corrected visual acuity worse than 20/60 as assessed by a pocket vision screening card</p>	<p>1) 6th grade level high-detail two-sided patient educational pamphlet to promote SDM; N=101</p>	<p>1) 5th grade level low-detail one-sided 'talk to your doctor' cue handout; N=101</p> <p>2) Pictured traditional food pyramid (attention control); N=101</p>	<p>Unclear/nr</p>

Partin, 2006 [55, 56] (Partin, 2004)	USA RCT, parallel Apr-Jun 2001 (recruitment) Funding: non-profit	General internal medicine Veterans' Affair Medical clinic, 4	Men veterans of at least 50 years of age, with no prostate cancer, scheduled for general internal medicine appointment at one of the four participating centres between April and June 2001	n.r.	1) 10th grade level 23-min mailed video "The PSA Decision: What YOU Need to Know" (developed by FIMDM); N=384	1) 6th grade level mailed pamphlet (developed for study); N=384 2) Usual care and whatever decision-making support provided in routine appointments; N=384	Social Cognitive Theory
Watson, 2006 [57]	UK (England and Wales) RCT, parallel Jan-Aug 2004 (recruitment) Funding: n.r.	General practices, 11	Men 40 to 75 years old, with no history of prostate cancer	n.r.	1) Brief patient DA leaflet ('PSA testing for prostate cancer—an information sheet for men considering a PSA test'; options' outcomes, clinical problem, outcome probability) + questionnaire; N=980	1) Control questionnaire only; N=980	DA production conformed to accepted standards for the provision of patient information
Myers, 2005 [58]	USA RCT, parallel Aug 1999 to Jul 2000 Funding: non-profit	Community-based primary care practice, 3	Men older than 40 (final sample: 40 to 69) years, of African-American origin, from the participating practices, with no history of prostate cancer or benign prostate hyperplasia, who had not undergone a prostate biopsy or prostate ultrasound, had visited one of the participating practices within two years prior to study initiation, and had contact information available at the practice and informed consent	n.r.	1) Enhanced intervention: informational booklet (mailed) (about prostate cancer options' outcomes) + decision education session (about clinical problem, explicit values clarification, guidance/coaching) by telephone (patients contacted by trained health educator by telephone 1 month after booklet mailing; N=121	1) Standard intervention: informational booklet (about prostate cancer clinical problem and options' outcomes); N=121	US Preventive Services Task Force (USPSTF)
Gatellari, 2003 [59]	AUS RCT, parallel Period, n.r. Funding: non-profit	Urban general practices, 13	Men 40 to 70 years old, sufficiently fluent in English, not diagnosed with prostate cancer, from 13 general practitioners (GPs) in urban Sydney	n.r.	1) Evidence-based booklet, 7.3- level Flesch–Kincaid, 32-page, 3085-word (with essential content to inform decision making about PSA screening, in quantitative data form with maximised readability; includes a section for patients to write down the questions they might have for their doctors and another section suggesting patients to discuss or ask questions to their doctors); N=126	1) Pamphlet, 11.2-level Flesch–Kincaid, 968-word, published by the Australian government (information to advise men of the agreed policy about PSA screening, in non-numerical data form); N=122	Unclear/n.r.
Frosch, 2003 [60, 61] (Frosch, 2001)	USA RCT, parallel	Preventive medicine clinic, 1	Men older than 50 years, who made an appointment at the clinic, who had broadband	n.r.	1) 47-slide, 25-30 min, web-based DA (without pause) mirroring videotape DA content; N=114	1) 23-minute video DA (dialog about options' outcomes, clinical problem, outcome	Unclear/n.r.

	Period, n.r. Funding: non-profit		Internet access at home or at work and informed consent			probability, others' opinions; N=112	
Volk, 2003 [62, 63] (Volk, 1999)	USA RCT, parallel Feb-Jun 1997 (enrollment) Funding: non-profit	University family medicine clinic, 1	Men 45 to 70 years old, with no history of prostate cancer and who presented for care at the participating centres, or patients with urinary incontinence or erectile dysfunction	n.r.	1) 20-minute educational videotape " the PSA decision: what you need to know" (developed by the foundation for informed medical decision making, Inc.) + accompanying brochure; N=80	1) No intervention at baseline (before visit) + brochure after 2 week follow-up; N=80	Shared Decision Making Approach
Schapira, 2000 [64]	USA RCT, parallel Period, n.r. Funding: non-profit	Veterans' Affair Medical Center Outpatient Clinic, 1	Men 50 to 80 years old with an outpatient (encounter) visit between 1990 to 1995 at the participating centre	Men with history of prostate or other cancer, previous prostate ultrasound study or biopsy, cystoscopy, prior prostate surgery, active genitourinary symptoms, cognitive impairment (defined by a mini-mental state examination score of 23 or less), an anticipated life expectancy of less than two years, or who were currently employed by the Veterans' Affair Medical Center	1) 8-page DA pamphlet with information about screening and treatment + educational (basic prostate cancer) information included in the comparator 5-page pamphlet; N=122	1) 5-page written pamphlet with basic information about prostate cancer (no information on risks and benefits of screening); N=135	Health Belief Model Theory
Davison, 1999 [65]	CAN RCT, parallel Period, n.r. Funding: non-profit	Family medical teaching Centre, 1	Men 50 to 79 years old, with a periodic health examination appointment with no previous history of prostate cancer or evidence of mental confusion, able to read, speak and write English; men previously screened for prostate cancer were also included	n.r.	1) Verbal and written information (about prostate cancer screening controversies, pros and cons of having DER and/or PSA) with encouragement to discuss with family physician and to participate in making a screening decision to the extent patients were comfortable); N=50	1) Attention control: discussion about general issues (prior to medical appointment and about the same length of time than intervention group); N=50	Unclear/n.r.

Wolf, 1998 [66, 67] (Wolf, 1996)	USA RCT, parallel Jun 1994 to Mar 1995 (recruitment) Funding: non-profit	University family practices, 4	Men of at least 50 years of age, English speakers visiting their primary care physicians for outpatient appointments, with no personal history of prostate cancer and who had not been screened with PSA, and with informed consent	Men with prior PSA screening and personal history of prostate cancer	1) Scripted overview of PSA screening; N=103	1) Brief control message about PSA availability; N=102	Health Belief Model Theory
TREATMENT							
Chabrera, 2015 [68]	SPN RCT, parallel Jun 2011 to Jun 2013 Funding: non-profit	University hospital, 1 Oncology institutes, 2	Men older than 45 years, newly diagnosed in the early stages of localized prostate cancer (T1Y2/N0/M0), not receiving therapeutic treatment for prostate cancer, and able to read and write in Spanish	Men having a primary tumor type different from prostate cancer, having been diagnosed for any type of cognitive deterioration, psychiatric or addictive disorders that would preclude taking part in the process of shared decision making, and unwillingness to give informed consent to participate in the study; and patients with stage t1an0m0 tumours, because their treatment consists of active follow-up until signs of disease progression, and hence there is no real choice of treatment	1) Printed booklet DA for localised prostate cancer with values' clarification exercises and with preparation material for consultation; N=73	1) Standard information for localised prostate cancer; N=74	Ottawa Decision Support Framework (ODSF)
Berry, 2013 [69-71] (Berry, 2012; Bosco, 2012)	USA RCT, parallel Mar 2007 to Nov 2009 Funding: non-profit	Veterans' Affair hospital, 3 University cancer centre, 1 Cancer centre institute, 2	Men older than 40 years, with T1 or T2, histologically-proven localised prostate cancer, were consulting with specialists who perceived that each participant was a candidate for at least 2 treatment options, and had not begun therapy	Men with advanced disease or those who had received prior treatment	1) Tailored internet aid: baseline validated questionnaires with the P3P assessment component and research measures + P3P printed education and text and interactive web video coaching tailored to patients' personal profile (video on options' outcomes, clinical problem, outcome probabilities, others' opinion, guidance (list of questions to ask doctor and automated summary); N=266	1) Website links to prostate cancer information: baseline validated questionnaires with the P3P assessment component and research measures + links to established information websites about prostate cancer; N=228	Ottawa Decision Support Framework (ODSF)

Hacking, 2013 [72]	UK (Scotland) RCT, parallel Jan 2009 to Aug 2010 (eligibility assessment) Funding: non-profit	General hospital, 1	Men who had just received a diagnosis of localised or early stage primary prostate cancer, those who had a decision to make regarding cancer management and who were referred to a specialist urology consultant; age not used as inclusion criteria; final sample 65.4 and 67.2 for intervention and control group respectively	Men with any cognitive or sensory impairment, which impeded participation in the trial, and those who had already opted for active monitoring or to commence hormone treatment at diagnosis	1) DA coaching - decisional navigator by telephone or in person to guide patients in preparing for a consultation (by identifying and framing key questions and concerns regarding cancer management options) to generate a tailored personal consultation plan for the appointment; N=63	1) Usual care pathway for prostate cancer patients meeting with a specialist consultant to discuss treatment options within a month of diagnosis; N=60	Situation, choices, objectives, people, evaluation, and decisions checklist (scoped)
van Tol-Geerdink, 2013 [73]	NLD RCT, parallel Mar 2008 to Feb 2011 Funding: non-profit	University medical centre, 1 General hospitals, 2	Men with primary localized prostate cancer (T1–3a0m0), intending to be treated and eligible for both radiotherapy and radical prostatectomy; age not selected as inclusion criteria; final sample age: 64 (SD5) years	Men with contra-indications for surgery (based on for example age or cardiovascular problems) or external radiotherapy (based on for example Crohn's disease), mental or cognitive problems as assessed by the physician, inadequate knowledge of the Dutch language or a preference for active surveillance. We excluded active surveillance patients because our decision aid did not include risk information on this option. Brachytherapy was offered only to a selected group of patients. Exclusion criteria for brachytherapy were a small or large prostate volume (<20 ml or >50 ml), PSA > 15, Gleason >7 and/or severe urinary symptoms (requiring medication or, if available, IPSS > 12 and/or Qmax < 15 ml/s).	1) DA consultation in semi-structured interview with researcher to provide information + discussion of treatment choice with (their) specialists; N=163	1) Usual care: discussion of treatment choice with (their) specialists; N=77	Ottawa Decision Support Framework (ODSF)
Huang, 2014 [74-76] (Auvinen, 2004; Auvinen, 2001)	FIN RCT, parallel Period, n.r. Funding: non-profit	University hospitals, 2 General hospitals, 2	Men with new histologically confirmed prostate cancer (between September 1993 and November 1994), with the ability to complete the study questionnaire, as judged by the urologist in charge of treatment, with no exclusion	Men with inability to participate because of dementia or strongly impaired general condition, and patients with stage t1a0m0 tumours, because their treatment consists of active follow-up until signs of	1) Enhanced participation: extensive consultation with urologist where patient-defined own role in treatment choice actively emphasised (with discussions about various aspects of available treatment options, including survival rate, adverse	1) Standard treatment protocols; N=106	Unclear/n.r.

			criteria based on age of the patient or extent of the disease; severe coronary heart disease for major surgery was not regarded as an exclusion criterion	disease progression, and hence there is no real choice of treatment	effects and cost, and the patient's opinion about the aims of treatment and willingness to accept potential side-effect) + oral and written structured information about treatment options; N=104		
Feldman-Stewart, 2012 [77-79] (Feldman-Stewart, 2004; Feldman-Stewart, 2001)	CAN RCT, parallel Period, n.r. Funding: non-profit	Cancer clinic centres, 4	Men older than 40 years, with newly diagnosed prostate cancer with low- or intermediate-risk early-stage disease (stage T1 or T2, prostate-specific antigen <20 and Gleason <8), visiting the cancer clinic for their first consultation and faced with making a treatment decision, understood English well-enough to complete the DA	Men with a cognitive or emotional challenge that would preclude him from using the patient DA in a meaningful manner or that it would be potentially harmful or upsetting to him, in the opinion of the treating physician	1) Computer DA and interview with well-structured information with Value Clarification Exercises (Val Ex); N=81	1) Computer DA and interview with well-structured information with general questions (selection of attributes); N=75	Differentiation and Consolidation Theory
Taylor, 2010 [80]	USA RCT, parallel Sep 2002 to Nov 2004 Funding: non-profit	University hospital, 1 Hospital centre, 1 Local prostate cancer support groups and newsletters	Men with newly diagnosed, early-stage prostate cancer (T1-T2N0M0; any Gleason score), English speakers, with absence of cognitive impairment, no prostate cancer history, treatment decision not yet made, and treatment choice not limited by comorbidities or age; no exclusion criteria based on age; final sample age: 64.6 (SD9.4) years	n.r.	1) 4hr information CD-Room + 3 interactive Decision Tools; N=66 (95 CD users)	1) Information only; N=66 (25 non-CD users)	Unclear/n.r.
Mishel, 2009 [81]	USA RCT, parallel Period, n.r. Funding: non-profit	Cancer centre, 2 Community hospital, 3 Veterans' Affairs Medical Center, 1	Men with staging (t1a, b, c or T2a or b); Gleason score less than 10; PSA level less than 20; at least 10 days before the treatment consultation appointment; no major cognitive impairment; ability to read; access to a telephone; no prior cancer history; and a primary support person designated by the patient who was willing to participate in the study	Men with advanced disease beyond stage t2b	1) Treatment supplemented: DVD + Booklet + 4 Telephone calls by (trained) nurse to both patients and patient primary supporting person (e.g. Spouse); N=89	1) Treatment direct: DVD + Booklet + 4 Telephone calls by (trained) nurse to patients only; N=93 2) control - usual care (?): handout on staying healthy during treatment; N=74	Uncertainty Illness Theory

Hack, 2007 [82]	CAN RCT, parallel Feb-Dec 2001 Funding: non-profit	Tertiary oncology clinic treatment facilities, 4	Men older than 18 years, newly diagnosed with prostate cancer, who were presenting to a tertiary oncology clinic for their primary treatment consultation, discerned to be free of any cognitive impairment that would disable them from providing informed consent	n.r.	1) Audiotape: a) audio recording of clinical encounter audio-taped and given to patient (t2); b) audio recording of clinical encounter: audio-taped and offered patient the choice of receiving audiotape or not (t3); N=214	1) No audiotape: a) audio recording of clinical encounter: audio-taped and not given to patient (t1); b) standard care: consultation not audio-taped; N=211	Unclear/n.r.
Davison, 2007 [83]	CAN RCT, parallel Period, n.r. Funding: non-profit	Prostate education and research centre within a general hospital, 1	Men newly diagnosed with localised prostate cancer, with biopsy-proven early-stage prostate cancer, who were aware of their diagnosis, had their initial urologic treatment consultation, not scheduled for definitive treatment within the next 4 weeks, and able to read and write English; age not selected as inclusion criteria; final sample 62.4 years (SD6.9); partners were included in the sessions if they accompanied the patient	n.r.	1) Individualized information printout based on information preferences and patient's disease characteristics + Written information package + Telephone by Research Nurse approximately 4 weeks later + Encouragement to bring their significant others to the appointment who were also included in the sessions; N=162	1) Generic information videotape + written information package + telephone by research nurse approximately 4 weeks later + encouragement to bring their significant others to the appointment who were also included in the sessions; N=162	The Decision Support Framework (by O'Connor)
Feldman-Stewart, 2006 [84]	CAN RCT, parallel Period, n.r. Funding: non-profit	Ambulatory cancer centres, 3	Men with stage 1 or 2 prostate cancer, PSA <20, Gleason score <8, emotionally and cognitively capable of completing the task (judged by the oncologist), and judged by themselves as being able to read English. Family members were eligible if they were older than 18 years	n.r.	1) 8th grade-Flesch-Kincaid CCE information booklet, developed by authors at cancer centre and designed for patients with low or intermediate risk disease; N=152	1) Standard information booklet routinely provided to patients, developed by AstraZeneca; N=156	Unclear/n.r.
Davison, 1997 [85]	CAN RCT, parallel Period, n.r. Funding: non-profit	Community clinic with practicing urologists, 1	Men newly diagnosed with prostate cancer, having been told their diagnosis: not having had their initial treatment consultation, able to read, speak, and write English, and with no evidence of mental confusion; age not selected as inclusion criteria; final sample age range: 41-81	n.r.	1) Empowerment intervention (interview preparing for consultation): Written information package (five brochures about prostate cancer) + Questions List to ask physicians (with discussion with investigator with additional questions prompted from discussions added to list) + Blank audiotape (to record consultation)	1) Written information package (five brochures about prostate cancer) + package content shown + recommendation to read the information before or after the initial treatment consultation with their physician + social component in the interview; N=30	Self-Efficacy Theory within The Empowerment Model (by Conger and Kanungo)

					+ Encouragement to participate in decision-making, and to bring their spouse/significant other(s) to the treatment consultation; N=30		
SCREENING AND TREATMENT							
Wilt, 2001 [86]	USA RCT, parallel Oct to Nov 1998 Funding: n.r.	Primary care clinic at a Veterans' Affair Medical Center, 1	Men of at least 50 years of age, attending a primary care clinic at a Veterans' Affair Medical Center	n.r.	1) 7th grade Fleisch-Kincaid Question and answer two-sided printed sheets; N=275	1) Usual care (control) alone; N=275	Unclear/n.r.